STANDARD COMMERCIAL AND NSA DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RISANKIZUMAB-RZAA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RISANKIZUMAB-RZAA	SKYRIZI	45699		GPI-10 (9025057070, 5250406070)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient had a trial of or contraindication to one or more forms of conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids (e.g., betamethasone dipropionate, clobetasol propionate), calcipotriene, acitretin, methotrexate, or cyclosporine

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient was previously stable on another biologic (e.g., Cimzia [certolizumab], Cosentyx [secukinumab]) and is switching to the requested drug
   - The patient has psoriasis covering 3% or more of body surface area (BSA)
   - The patient has psoriatic lesions affecting the hands, feet, face, or genital area

   If yes, **approve the requested strength and dosage form for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   <u>FIRST APPROVAL:</u>
   - **150mg/1.66mL Kit: Approve for 1 month with a quantity limit of #1 kit (2 syringes) per 28 days.**
   - **150mg/mL pen/syringe: Approve for 1 month with a quantity limit of #1mL per 28 days.**

   <u>SECOND APPROVAL:</u>
   - **150mg/1.66mL Kit: Approve for 5 months with a quantity limit of #1 kit (2 syringes) per 84 days (Please enter a start date of 3 WEEKS AFTER the START date of the first approval).**
   - **150mg/mL pen/syringe: Approve for 5 months with a quantity limit of #1mL per 84 days. (Please enter a start date of 3 WEEKS AFTER the START date of the first approval).**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   - The patient had a trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **approve the requested strength and dosage form for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   FIRST APPROVAL:
   - **150mg/1.66mL Kit: Approve for 1 month with a quantity limit of #1 kit (2 syringes) per 28 days.**
   - **150mg/mL pen/syringe: Approve for 1 month with a quantity limit of #1mL per 28 days.**

   SECOND APPROVAL:
   - **150mg/1.66mL Kit: Approve for 5 months with a quantity limit of #1 kit (2 syringes) per 84 days (Please enter a start date of 3 WEEKS AFTER the START date of the first approval).**
   - **150mg/mL pen/syringe: Approve for 5 months with a quantity limit of #1mL per 84 days. (Please enter a start date of 3 WEEKS AFTER the START date of the first approval).**

   If no, continue to #4.

3. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The patient had a trial of or contraindication to ONE conventional agent, such as corticosteroids (e.g., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RISANKIZUMAB-RZAA

INITIAL CRITERIA (CONTINUED)

4. Is the prescriber requesting an intravenous infusion induction dose of **Skyrizi 600mg/10mL?**

If yes, approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:
FIRST APPROVAL:
- **600mg/10mL: Approve for 3 months with a quantity limit of #10mL per 28 days.**

SECOND APPROVAL (approve the requested strength):
- **180mg/1.2mL: Approve for 3 months with a quantity limit of #1.2 mL per 56 days (Please enter start date of 11 WEEKS AFTER the START date of the first approval).**
- **360mg/2.4mL: Approve for 3 months with a quantity limit of #2.4 mL per 56 days (Please enter start date of 11 WEEKS AFTER the START date of the first approval).**

If no, **approve a maintenance dose for 6 months by GPID or GPI-14 for the requested strength as follows:**
- **180mg/1.2mL: #1.2mL per 56 days.**
- **360mg/2.4mL: #2.4mL per 56 days.**

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RISANKIZUMAB-RZAA (Skyrizi)** requires the following rules be met for approval:
A. You have ONE of the following diagnoses:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe Crohn's disease (CD: a type of bowel disorder)

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RISANKIZUMAB-RZAA

INITIAL CRITERIA (CONTINUED)

B. **If you have moderate to severe plaque psoriasis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You have tried or have a contraindication (harmful for) to one or more forms of standard therapies, such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids (such as betamethasone dipropionate, clobetasol propionate), calcipotriene, acitretin, methotrexate, or cyclosporine
   4. You meet ONE of the following:
      a. You were previously stable on another biologic (such as Cimzia [certolizumab], Cosentyx [secukinumab]) and are switching to the requested drug
      b. You have psoriasis covering 3% or more of body surface area (BSA)
      c. You have psoriatic lesions (rashes) affecting the hands, feet, genital area, or face

C. **If you have psoriatic arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You have tried or have a contraindication (harmful for) to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

D. **If you have moderate to severe Crohn's disease, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
   3. You had a trial of or contraindication (harmful for) to ONE standard therapy, such as corticosteroids (such as budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RISANKIZUMAB-RZAA

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) **AND** meet the following criterion?
   - The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

   If yes, **approve the requested strength and dosage form for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **150mg/1.66mL Kit: #1 kit (2 syringes) per 84 days.**
   - **150mg/mL pen/syringe: #1mL per 84 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve the requested strength and dosage form for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **150mg/1.66mL Kit: #1 kit (2 syringes) per 84 days.**
   - **150mg/mL pen/syringe: #1mL per 84 days.**

   If no, continue to #3.

3. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD)?

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **180mg/1.2mL: #1.2mL per 56 days.**
   - **360mg/2.4mL: #2.4mL per 56 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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RISANKIZUMAB-RZAA

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RISANKIZUMAB-RZAA (Skyrizi)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe Crohn's disease (CD: a type of bowel disorder)

B. **If you have moderate to severe plaque psoriasis, renewal also requires:**
   1. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

C. **If you have psoriatic arthritis, renewal also requires:**
   1. You experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Skyrizi.

REFERENCES

- Skyrizi [Prescribing Information]. North Chicago, IL: AbbVie, Inc.; December 2022.

Library	Commercial	NSA
Yes	Yes	Yes

Part D Effective: N/A
Commercial Effective: 07/01/23
Created: 05/19
Client Approval: 05/23
P&T Approval: 04/23